SEP 1 8 2001

K011929

## 510(k) SAFETY AND EFFECTIVENESS SUMMARY

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|---|---|
| Trade Name: | Aaron A910 Handpiece Sheath |
| Common Name: | Handpiece Sheath |
| Classification Name: | Electrosurgical Cutting and Coagulation Devices and Accessories (per 21CFR 878.4400) |

The **Aaron A910 Handpiece Sheath** is a non-sterile, disposable electrosurgical handpiece cover that is designed to fit over an electrosurgical handpiece to provide a barrier between the handpiece and the patient, thus prevent contamination of the handpiece.

The **Aaron A910 Handpiece Sheath** is substantially equivalent to the Geiger Medical Technologies Handpiece Sheath (K-992149), the Banta Healthcare Sanitherm Thermometer Sheath (K983406), and the Aspen Laboratories/Conmed Handpiece Sheath (K-963088). Additionally, the sheath is of the same design, intended use, materials, method of preparation, and performance claims as Aaron Medical High Temperature Replacement Tip drape (K-945758).

Hazard analysis evaluations were performed on the **Aaron A910**. There are no new hazards presented with the use of the **Aaron A910** as compared with the predicate devices.

In conclusion, the **Aaron A910** Handpiece Sheath is substantially equivalent to the named predicate devices in design, methods of operation, intended use, materials, and method of preparation.

Submitted By: Richard Kozloff
Vice-President ; Quality Assurance
Aaron Medical
7100 30th Avenue North
St. Petersburg, FL 33710

Contact Person: Richard Kozloff
**Date:** **June 19, 2001**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 8 2001

Mr. Richard Kozloff
Vice President, Quality Assurance
Aaron Medical, Inc.
7100 30th Avenue North
St. Petersburg, Florida 33710

Re: K011929
Trade/Device Name: Aaron A910 Handpiece Sheath
Regulation Number: 878.4400
Regulatory Class: II
Product Code: GEI
Dated: June 19, 2001
Received: June 20, 2001

Dear Mr. Kozloff:

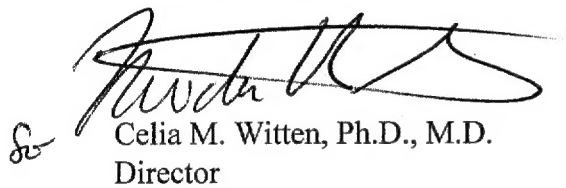
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**AARON MEDICAL INDUSTRIES**
**AARON 910 HANDPIECE SHEATH**

**510 (K) NOTIFICATION**

## INDICATIONS FOR USE

510(k) Number (if known): K011929

**Device Name:** Aaron A910 Handpiece Sheath

Indications for Use:

The Aaron 910 handpiece Sheath is intended to be used as an accessory to electrosurgical handpieces. The sheath is placed over the handpiece and provides a barrier to minimize contamination. The Handpiece Sheath is non-sterile and is intended for single patient use only.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011929

(Optional Format 3-10-98)